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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/791,112	03/02/2004	Thomas M. Wascher	7899	2457

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EXAMINER	
TYSON, MELANIE RUANO	

ART UNIT	PAPER NUMBER
3731	

DATE MAILED: 07/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/791,112	WASCHER, THOMAS M.	
	Examiner	Art Unit	
	Melanie Tyson	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) *15-33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/2/04 & 6/7/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I in the reply filed on June 9, 2006 is acknowledged. The traversal is on the ground(s) that Groups I and II were not shown to be distinct. The applicant states that the flexible catheter is sized to removably fit on a stereotaxy system probe. Therefore, the only practical way of using the flexible marking catheter is to use a frameless stereotaxy system to position the flexible marking catheter in the body. This is not found persuasive because the inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the product as claimed can be used in a materially different process of using that product. Although the flexible marking catheter is sized to removably fit on a stereotaxy system probe, the flexible marking catheter can be used by itself to measure the depth of an organ. During surgery, for example, a surgeon can use his hands to place the marking catheter adjacent to an organ to be measured.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 15-33 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on June 9, 2006.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Kieturakis (Patent No. 5,787,897).

Regarding claim 1, Kieturakis discloses a flexible catheter body (since the sheath is a thin flexible tube; Figure 6, element 18) made of a flexible material (latex; column 5, lines 24-26) and having a closed distal end (92) and an open proximal end (91). The diameter of the lumen (96) may be constructed with any suitable dimension to accommodate an instrument (column 5, lines 34-37). Therefore, the flexible catheter body (18) is inherently capable of being sized to removably fit on a frameless stereotaxy system probe such that the catheter (18) is positioned in a body using the probe and such that the probe is removable from the catheter without moving the catheter after the catheter is positioned in the body using the probe.

Regarding claim 3, Figure 6 shows a flange (collar; 94) at the open proximal end of the flexible catheter body (18) that is inherently capable of facilitating the removal of the probe from the catheter (18) after the catheter (18) is positioned in the body using the probe (Kieturakis discloses the flange 94 is adapted for grasping with fingers; column 5, lines 30-32).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kieturakis in view of Schneiter (Patent No. 6,533,763 B1).

Kieturakis discloses a flexible catheter as described in the claims above; however, Kieturakis does not disclose the body is made of silicone. Like Kieturakis, Schneiter discloses a flexible catheter (Figure 1, element 12). Unlike Kieturakis, Schneiter discloses the body of the flexible catheter (12) is made of silicone (column 3, lines 46-48) for its resilient and biocompatible properties (column 3, lines 46-48). Therefore, to construct the catheter body of Kieturakis from silicone as taught by Schneiter would have been obvious to one of ordinary skill in the art at the time the invention was made so that the catheter body is flexible and biocompatible.

8. Claims 4-7, 9, and 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kieturakis in view of Clark et al. (Patent No. 6,613,002 B1).

Regarding claim 4, Kieturakis discloses a flexible catheter as described in the claims above; however, Kieturakis does not disclose length indicia on an outer surface of the flexible catheter body. Clark et al. disclose a system of indicia (Figure 1, element 59) for a catheter or other medical device (10; column 2, lines 16-17). Figure 1 shows the indicia (59) are visible on an outer surface of the catheter (10) indicating distances along the catheter body from the distal end thereof (column 4, lines 32-33).

Regarding claim 5, Clark et al. disclose the length indicia (59) may indicate centimeter distances along the catheter (10) body from the distal end thereof (column 4, lines 29-31).

Regarding claim 6, Clark et al. disclose the length indicia (59) include rings (17) visible around an outer surface of the flexible catheter (10) body at 5 centimeters from the distal end thereof and at 10 centimeters from the distal end thereof. Figure 1 shows the indicia (59) are visible on the outer surface of the flexible catheter (10) body at one, two, three, four, six, seven, eight, and nine centimeters from the distal end thereof and they may be in the form of dots (column 1, lines 19-21).

Regarding claim 7, Clark et al. disclose the length indicia include a double ring (18) visible around the outer surface of the flexible catheter (10) body at ten centimeters from the distal end thereof.

Clark et al. teach that a system of indicia for a catheter or other medical device helps to aid the physician in proper placement of the catheter (10) or other medical

device in the body of a patient during a medical procedure (column 1, lines 16-19). Therefore, to construct the flexible catheter of Kieturakis with indicia as taught by Clark et al. would have been obvious to one of ordinary skill in the art at the time the invention was made in order to facilitate proper placement of the catheter in the body.

Regarding claim 9, Kieturakis discloses a flexible catheter body (since the sheath is a thin flexible tube; Figure 6, element 18) made of a flexible material (latex; column 5, lines 24-26) and having a closed distal end (92) and an open proximal end (91). The diameter of the lumen (96) may be constructed with any suitable dimension to accommodate an instrument (column 5, lines 34-37). Therefore, the flexible catheter body (18) is inherently capable of being sized to removably fit on a frameless stereotaxy system probe such that the catheter (18) is positioned in a body using the probe and such that the probe is removable from the catheter without moving the catheter after the catheter is positioned in the body using the probe. Figure 6 shows a flange (collar; 94) at the open proximal end of the flexible catheter body (18) that is inherently capable of facilitating the removal of the probe from the catheter (18) after the catheter (18) is positioned in the body using the probe (Kieturakis discloses the flange 94 is adapted for grasping with fingers; column 5, lines 30-32).

Kieturakis does not disclose length indicia visible on an outer surface of the flexible catheter (10) body. Clark et al. disclose a system of indicia (Figure 1, element 59) for a catheter or other medical device (10; column 2, lines 16-17). Figure 1 shows the indicia (59) are visible on an outer surface of the catheter (10) indicating distances along the catheter body from the distal end thereof (column 4, lines 32-33).

Regarding claim 11, Clark et al. disclose the length indicia (59) may indicate centimeter distances along the catheter (10) body from the distal end thereof (column 4, lines 29-31).

Regarding claim 12, Clark et al. disclose the length indicia (59) include rings (17) visible around an outer surface of the flexible catheter (10) body at 5 centimeters from the distal end thereof and at 10 centimeters from the distal end thereof. Figure 1 shows the indicia (59) are visible on the outer surface of the flexible catheter (10) body at one, two, three, four, six, seven, eight, and nine centimeters from the distal end thereof and they may be in the form of dots (column 1, lines 19-21).

Regarding claim 13, Clark et al. disclose the length indicia include a double ring (18) visible around the outer surface of the flexible catheter (10) body at ten centimeters from the distal end thereof.

Clark et al. teach that a system of indicia for a catheter or other medical device helps to aid the physician in proper placement of the catheter (10) or other medical device in the body of a patient during a medical procedure (column 1, lines 16-19). Therefore, to construct the flexible catheter of Kieturakis with indicia as taught by Clark et al. would have been obvious to one of ordinary skill in the art at the time the invention was made in order to facilitate proper placement of the catheter in the body.

9. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kieturakis in view of Rafelson (Patent No. 4,662,871).

Kieturakis discloses a flexible catheter as described in the claims above; however, Kieturakis does not disclose that the flexible catheter body is made of a

brightly colored material. Like Kieturakis, Rafelson discloses a flexible catheter (Figure 1, element 1). Unlike Kieturakis, Rafelson discloses the flexible catheter (1) body is made of brightly colored material in order to provide a sharp contrast to the white backgrounds normally found in hospitals (column 6, lines 33-39). Therefore, to construct the flexible catheter body of Kieturakis of a brightly colored material would have been obvious to one of ordinary skill in the art at the time the invention was made to allow for easy recognition of the catheter in dark, poorly lit environments often necessary for many medical procedures (column 6, lines 33-39).

10. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kieturakis in view of Clark et al. as applied to the claims above, and further in view of Schneiter.

Kieturakis in view of Clark et al. discloses a flexible catheter as described in the claims above; however, Kieturakis in view of Clark et al. does not disclose the body is made of silicone. Like Kieturakis in view of Clark et al., Schneiter discloses a flexible catheter (Figure 1, element 12). Unlike Kieturakis in view of Clark et al., Schneiter discloses the body of the flexible catheter (12) is made of silicone (column 3, lines 46-48) for its resilient and biocompatible properties (column 3, lines 46-48). Therefore, to construct the catheter body of Kieturakis in view of Clark et al. from silicone as taught by Schneiter would have been obvious to one of ordinary skill in the art at the time the invention was made so that the body is flexible and biocompatible.

11. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kieturakis in view of Clark et al. as applied to the claims above, and further in view of Rafelson.

Kieturakis in view of Clark et al. discloses a flexible catheter as described in the claims above; however, Kieturakis in view of Clark et al. does not disclose that the flexible catheter body is made of a brightly colored material. Like Kieturakis in view of Clark et al., Rafelson discloses a flexible catheter (Figure 1, element 1). Unlike Kieturakis in view of Clark et al., Rafelson discloses the flexible catheter (1) body is made of brightly colored material in order to provide a sharp contrast to the white backgrounds normally found in hospitals (column 6, lines 33-39). Therefore, to construct the flexible catheter body of Kieturakis in view of Clark et al. of a brightly colored material would have been obvious to one of ordinary skill in the art at the time the invention was made to allow for easy recognition of the catheter in dark, poorly lit environments often necessary for many medical procedures (column 6, lines 33-39).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Tyson whose telephone number is (571) 272-9062. The examiner can normally be reached on Monday through Thursday 7:30 a.m. - 5:00 p.m., alternate Fridays 7:30 a.m. - 4:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie Tyson MT
June 22, 2006

ANHTUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER
6/24/06.